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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,508	03/26/2004	Xing Cheng	. 26-003820US	8613

22798 7590 01/11/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/811,508	<b>Applicant(s)</b> CHENG ET AL.	
	<b>Examiner</b> Stacy B. Chen	<b>Art Unit</b> 1648	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,6,10-12,14-16,19,20,27,35,39,46-48,53,60 and 66 is/are pending in the application.
- 4a) Of the above claim(s) 35,39,46-48,53,60 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,10-12,14-16,19,20 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/26/04, 1/10/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>Sequence Alignment</u>                 |

### **DETAILED ACTION**

1. Applicant's election with traverse of Group I and SEQ ID NO: 10, 12 and 14, is acknowledged and entered. Claims 1, 2, 4, 6, 10-12, 14-16, 19, 20, 27, 35, 39, 46-48, 53, 60 and 66 are pending. Claims 1, 2, 4, 6, 10-11, 14-16, 19, 20 and 27 are under examination with respect to SEQ ID NO: 9 and 10, respectively. Claims 12 and 15 are drawn to embodiments encompassing non-elected sequence SEQ ID NO: 12. Claims 12 and 15 are thereby withdrawn from consideration, being drawn to a non-elected invention.

Applicant argues that the restriction between SEQ ID NO: 14-19 is improper because the claims require that the claimed sequence not be present in SEQ ID NO: 14-19. Therefore, the restriction requirement between SEQ ID NO: 14-19 is withdrawn.

In summary, the restriction requirement is deemed proper and made FINAL.

### ***Oath/Declaration***

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). In particular, Hyun Jung Park's address has been altered. Correction is required.

### ***Drawings***

3. The drawings are objected to for depicting DNA sequences that are not properly identified by a SEQ ID NO. Correction is required.

***Claim Objections***

4. Claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20 and 27 are objected to because claim 1 and all dependent claims recite, "BLASTN". This acronym should be spelled out at its first recitation.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite, "as determined by BLASTN using default parameters". The term "default" in claim 1 and all dependent claims is a relative term which renders the claim indefinite. The term "default" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Further, "conservative" variations and "conservative" substituted amino acid residues are unclear terms. The term "conservative" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Correction is required to overcome this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 6, 10, 11, 14, 16, 19, 20 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to an isolated or recombinant nucleic acid comprising a polynucleotide sequence that is greater than 97.8% identical to SEQ ID NO: 1, or a complementary sequence thereof. Another embodiment is a polynucleotide sequence encoding an amino acid sequence or unique subsequence selected from the group consisting of SEQ ID NO: 2-11 or an artificial conservative variation thereof. The claims encompass a large genus of polynucleotide sequences that have not been adequately described such that one of skill in the art would be in possession of the full scope of the invention as claimed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity, 97.8% identity to SEQ ID NO: 1. SEQ ID NO: 1 has 15,225 nucleotides. The number of possible variants that fall within 97.8% is so great that there is not a representative number of variants in the specification such

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that Applicant was possession of the large genus of polynucleotides. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 2, 4, 6, 10, 11, 16, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Karron *et al.* (*PNAS USA*, 1997, 94:13961-13966, "Karron"). The claims are drawn to an isolated or recombinant nucleic acid comprising a polynucleotide selected from the group consisting of a) SEQ ID NO: 1 or a complementary polynucleotide sequence thereof, b) a polynucleotide sequence that is greater than 97.8% identical to SEQ ID NO: 1 or a complement thereof, c) a polynucleotide sequence comprising at least one unique polynucleotide subsequence comprising at least 10 contiguous nucleotides of SEQ ID NO: 1 or a complement thereof with the proviso that a polynucleotide subsequence includes at least one subsequence not included in SEQ ID NO: 14-19 or a complement thereof; and d) a polynucleotide sequence encoding an amino acid sequence or unique subsequence selected from the group consisting of SEQ ID NO: 2-11 or an artificial conservative variation thereof. The nucleic acid is DNA, cDNA, RNA or an artificial nucleic acid. The sequence of b) wherein the polynucleotide is at least 98.5% identical to SEQ ID NO: 1 or a complement thereof. Also claimed is a nucleotide sequence that comprises at least one artificially mutated nucleotide. The nucleic acid has at least 20-200 contiguous amino acid residues of SEQ ID NO: 9 or 10.

Karron teaches a polynucleotide sequence that is 99.4% identical to Applicant's SEQ ID NO: 9, encoding an M2-1 ORF (see attached sequence alignment). Karron discloses a live, cold-passaged candidate vaccine virus that lacks the SH and G proteins (abstract). Given the great degree of variation within SEQ ID NO: 1, as claimed in claims 1, 2, 4, 6, 10, 11, 16, 19 and 20, Karron's polynucleotide anticipates the claimed embodiments.

***Conclusion***

8. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

*Stacy B. Chen*

Stacy B. Chen

January 9, 2006



GenCore version 5.1.6  
Copyright (c) 1993 - 2005 Compugen Ltd.

OM protein - protein search, using sw model

Run on: December 27, 2005, 14:01:48 ; Search time 199.74 Seconds  
(without alignments)  
688.787 Million cell updates/sec

Title: US-10-811-508-9

Perfect score: 1013

Sequence: 1 MSRRNCKFEIRGHCLNRR.....PKSTVNDQDQTKNDITG 195

Scoring table:

BLOSUM62

Gapop 10.0 , Gapext 0.5

Searched: 2166443 seqs, 705528306 residues

Total number of hits satisfying chosen parameters: 2166443

Minimum DB seq length: 0

Maximum DB seq length: 2000000000

Post-processing: Minimum Match 0%

Maximum Match 100%

Listing first 45 summaries

Database :

Uniprot\_05\_80.\*

1: uniprot\_sprot.\*

2: uniprot\_trembl.\*

Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

Result No.	Score	Query Match %	Length	DB ID	Description
1	1013	100.0	195	2	Q6V2E6_HRSV
2	1007	99.4	195	2	Q42050_HRSV
3	952	94.0	194	2	Q76TK9_9MONO
4	952	94.0	194	2	Q84196_HRSV
5	950	93.8	194	1	VMA2_HRSVA
6	950	93.8	194	2	Q77TA8_HRSV
7	944	93.2	194	2	Q4KRW3_HRSV
8	830	81.9	186	1	VMA2_ORSVW
9	819	80.8	186	2	Q77K27_BRSVA
10	819	80.8	186	2	Q9Y823_9MONO
11	809	79.9	186	1	VMA2_BRSVA
12	809	79.9	186	2	Q77KF9_BRSVA
13	383	37.8	176	2	Q5MKN9_9MONO
14	383	37.8	176	2	Q50EW4_9MONO
15	383	37.8	176	2	Q5MKM1_MPV15
16	376	37.1	186	1	VMA2_TRTV
17	376	37.1	186	2	Q5USR0_9MONO
18	374	36.9	184	2	Q91R59_9MONO
19	373	36.8	184	2	Q91011_9MONO
20	373	36.8	184	2	Q91R55_9MONO
21	373	36.8	184	2	Q91C88_9MONO
22	372	36.7	184	2	Q91R62_9MONO
23	371	36.6	184	2	Q91R57_9MONO
24	369	36.4	184	2	Q9QF46_9MONO
25	367	36.2	184	2	Q91R54_9MONO
26	367	36.2	184	2	Q91R56_9MONO
27	364	35.9	186	2	Q8JJU6_TRTV
28	361	35.6	184	2	Q91R60_9MONO
29	359	35.4	187	2	Q6QKH2_9MONO
30	358	35.3	186	2	Q91SF9_9MONO
31	357	35.2	187	2	Q8QN58_9MONO

32	356	35.1	187	2	Q6QGG4_9MONO	Q6qgg4 human metap
33	355.5	35.1	187	2	Q6WBA6_9MONO	Q6wba6 human metap
34	354	34.9	187	2	Q6QQI8_9MONO	Q6qqi8 human metap
35	352.5	34.8	192	2	Q6E7G0_9MONO	Q6e7g0 human metap
36	351.5	34.7	187	2	Q6QGF6_9MONO	Q6qgf6 human metap
37	351	34.6	187	2	Q6WB97_9MONO	Q6wb97 human metap
38	348	34.4	187	2	Q6QES8_9MONO	Q6qes8 human metap
39	347	34.3	184	2	Q91R61_9MONO	Q91r61 avian pneum
40	342	33.8	184	2	Q91R58_9MONO	Q91r58 avian pneum
41	120.5	11.9	735	2	Q421W3_PLABE	Q421w3 plasmodium
42	117.5	11.6	1740	2	Q81JK9_PLAF7	Q81jk9 plasmodium
43	117.5	11.6	1710	2	Q81L30_PLAF7	Q81l30 plasmodium
44	114	11.3	2798	1	NPBL_MOUSE	Q8kcd5 mus musculus
45	112	11.1	846	2	Q4Y6I2_PLACH	Q4y6i2 plasmodium

ALIGNMENTS

RESULT 1						
Q6V2E6_HRSV						
ID	Q6V2E6_HRSV	PRELIMINARY;				
AC	Q6V2E6;					
DT	05-JUL-2004	(T-EMBLrel. 27, Created)				
DT	05-JUL-2004	(T-EMBLrel. 27, Last sequence update)				
DT	05-JUL-2004	(T-EMBLrel. 27, Last annotation update)				
DE	M2-1.					
OS	Human Respiratory syncytial virus 9320.					
OC	Viruses; ssRNA negative-strand viruses; Mononegavirales;					
OC	Paramyxoviridae; Pneumovirinae; Pneumovirus.					
OX	NCBI_TaxID=253182;					
RN	[1]					
RP	NUCLEOTIDE SEQUENCE.					
RA	Cheng X., Park H., Jin H.;					
RL	Submitted (JUL-2003) to the EMBL/GenBank/DBJ databases.					
DR	EMBL; AK353550; AAK14267.1; -; Genomic RNA.					
DR	GO; GO:0019031; C:Viral envelope; IEA.					
DR	GO; GO:0003676; F:Nucleic acid binding; IEA.					
DR	GO; GO:0005198; F:Structural molecule activity; IEA.					
DR	GO; GO:0046782; P:regulation of viral transcription; IEA.					
DR	InterPro; IPR009452; Pneumovirus_M2.					
DR	InterPro; IPR000571; Znf_CCH.					
DR	Pfam; PF06436; Pneumovirus_M2; 1.					
DR	Pfam; PF00642; zf-CCH; 1.					
SQ	SEQUENCE 195 AA; 22297 MW; 1PFEID88E00C2A14 CRC64;					
Query Match	100.0%; Score 1013; DB 2; Length 195;					
Best Local Similarity	100.0%; Pred. No. 9.9e-67;					
Matches 195; Conservative	0; Mismatches 0; Indels 0; Gaps 0;					
QY	1 MSRRNCKFEIRGHCLNRRCHYSHYFEPHPHALLVRQNFMLNKLKSMDSIDTLSEI 60					
DB	1 MSRRNCKFEIRGHCLNRRCHYSHYFEPHPHALLVRQNFMLNKLKSMDSIDTLSEI 60					
QY	61 SGAAELDRTEYALGVGVLESYIGSINNITKQACVAMSKLLIEINSDDIKCLRDNREP 120					
DB	61 SGAAELDRTEYALGVGVLESYIGSINNITKQACVAMSKLLIEINSDDIKCLRDNREP 120					
QY	121 NSPKIRVNTVISYIESNRKNKQTHLLKRLPADVLKTKIKNTLDIHKSITISNPKEST 180					
DB	121 NSPKIRVNTVISYIESNRKNKQTHLLKRLPADVLKTKIKNTLDIHKSITISNPKEST 180					
QY	181 VNDQNDQTKNDITG 195					
DB	181 VNDQNDQTKNDITG 195					
RESULT 2						
Q42050_HRSV						
ID	Q42050_HRSV	PRELIMINARY;				
AC	Q42050;					
DT	01-JAN-1998	(T-EMBLrel. 05, Created)				
DT	01-JAN-1998	(T-EMBLrel. 05, Last sequence update)				